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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,121	09/19/2003	Lyle Aaron Margulies	PTS103	8431
20482	7590	08/31/2005	EXAMINER	
GARRISON ASSOCIATES 2001 SIXTH AVENUE SUITE 3300 SEATTLE, WA 981212522			NATARAJAN, VIVEK	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/666,121	<b>Applicant(s)</b> MARGULIES ET AL.	
	<b>Examiner</b> Vivek Natarajan	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.  
4a) Of the above claim(s) 10 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11 and 13-17 is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/24/04</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9 and 11-17, drawn to an apparatus and method for monitoring human ANS activity using pulsatile blood volume waveform signals, classified in class 600, subclass 324.
  - II. Claim 10, drawn to an apparatus for monitoring human ANS activity using pulsatile blood volume waveform signals, classified in class 600, subclass 324.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the apparatus in Claim 10 does not include an artifact rejection algorithm for eliminating slope values less than one, as disclosed in Claim 1. The subcombination has utility with other combinations, such as being directly plugged into an electrical outlet rather than being connected to a battery power supply.

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3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Mr. David Garrison on 8/29/05, a provisional election was made without traverse to prosecute the invention of Group I, Claims 1-9 and 11-17. Affirmation of this election must be made by applicant in replying to this Office action. Claim 10 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Information Disclosure Statement***

5. The listing of references in the specification is not a proper information disclosure statement. The following references are listed in the specification but not in the information disclosure statement: US Patent Nos. 5,398,682; 6,529,752; and 6,580,944. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Claim Objections***

6. Claim 3 is objected to because of the following informalities: the term "whereby" should be replaced by "wherein" so as to positively set forth the claim limitation that no direct contact with a body part is required
7. Claim 12 is objected to because of the following informalities: the term "whereby" should be replaced by "wherein" so as to positively set forth the claim limitation that low and high frequency signal components are eliminated. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
9. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynn (US Patent No. 5,605,151) in view of Taylor et al. (US Patent No. 4,859,057).
10. Regarding Claim 1, Lynn discloses an apparatus (Figure 1) for diagnosing sleep apnea using a conventional photoplethysmographic pulse oximetry system 10 for deriving and utilizing the analysis of graphical pulse oximetry-derived waveforms as a function of time (col.3, lines 58-65). The system includes a pulse oximeter 12 with a photoplethysmographic probe 13 to record oxygen saturation and pulse data for a finger, which are both parameters that are indicative of changes in blood volume. The

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probe is connected to a microprocessor 20, which records the output signal and implements the following algorithm: the descending and ascending slopes of the waveform are calculated, slopes not falling within a specified finite range are discarded and not further processed, and the slopes are normalized by calculating a slope ratio of descending to ascending slopes (col.11, line 50 – col.12, line 20). It would have been obvious to one with ordinary skill in the art at the time the invention was made to select the parameters for normalization and artifact rejection to implement these steps according to the requirements disclosed by Lynn, including to select values such that resulting slope values less than one are eliminated from further processing.

11. Lynn also does not disclose amplifier and filter circuitry as part of the apparatus. Taylor et al. teach a pulse oximeter apparatus comprising an emitter, detector, and amplifier and filter circuitry for processing the output signals of the oximeter probe (col.2, lines 58-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus as disclosed by Lynn to include amplifier and filter circuitry as taught by Taylor since this allows for further processing of the output signal of the oximeter probe.

12. Regarding Claim 2, Lynn discloses that the probe is adapted for application on a finger (col.6, lines 43-45).

13. Regarding Claim 3, Lynn shows (see figure 1) that the photoplethysmographic probe 13 is adapted for indirect application to the finger 16, such that it is not in direct contact with the body part.

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14. Regarding Claims 4-7, the apparatus of Lynn includes a printer 24 (figure 1) for visual indication of output signals. The printer displays pulsatile oxygen saturation waveform signals, which are indicative of blood volume. Furthermore, the printer displays information representative of slopes and slope ratios (see figure 6 and the description thereof in col.14, line 55 – col.15, line 39).

15. Regarding Claims 8-9, Lynn discloses an audio processor 32 (figure 1) as part of the pulse oximetry system, for digitally recording sound data. Furthermore, Lynn indicates that any commercially available removable computer memory media can be used to download data collected by the system and transfer it to a separate processing unit for analysis (col.13, lines 44-58).

***Allowable Subject Matter***

16. The following is an examiner's statement of reasons for allowance: Applicant discloses a method for identification of human autonomic nervous system activity. There are several disclosures in the prior art (see Lynn as referred to in paragraph 7 above) that teach a method for monitoring human ANS activity comprising disposing a photoplethysmographic probe proximate to an adrenergic receptor site of a body part to obtain an electrical signal representative of a pulsatile blood volume waveform. The prior art also teaches a method of using slope detection algorithms to analyze said waveforms and subsequently display the resulting slope values via various data outputs, but this analysis is limited to after the signals have been processed. The prior art does not teach or suggest a method for monitoring ANS activity in which a time

interval for calculation of slope of the blood volume waveform is defined, and after which an algorithm for calculation and analysis of the waveform slope is implemented continuously in real-time, in combination with the other claimed steps.

17. Claims 11 and 13-17 are allowed.

18. Claim 12 would be allowable if rewritten or amended to overcome the objection set forth in this Office action.

19. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivek Natarajan whose telephone number is (571)272-6249. The examiner can normally be reached on Mon-Fri, 8:00-4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VN



ERIC F. WINAKUR  
PRIMARY EXAMINER